REMARKS

Objection to the claims:

Claims 25 and 26 have been amended to obviate the objections.

Rejection of the Claims under 35 USC § 112:

Claims 1-12, 25, and 26 have been amended to obviate the rejections. The claims have been amended to set forth the terminal process state that clearly relates back to the preamble. Claim 1 has been rewritten as a series of process steps.

Double Patenting:

Claims 1, 10, 12, and 26 have been rejected under the judicially created doctrine of obviousness type-double patenting as being unpatentable over claim 66 of copending Application No. 10/202,858. Applicants have amended the claims to obviate the rejection. Specifically, applicants have amended claims 1 and 25 to limit the process to intravascular delivery of the nucleic acid. The amendments incorporate previous claims 5 and 12 into claims 1 and 25. It is the Applicants' opinion that 10/202,858 only contemplates direct injection of naked DNA into a tissue.

Rejection of the claims under 35 USC §102:

Claims 1-3, 6-12 and 25-27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al 1997 and Chen et al 1998. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is Applicants' opinion that Jones and Chen both teach oral delivery of nucleic acid and do not contemplate intravascular delivery. Intravascular delivery of nucleic acid is further described in nonprovisional application serial number 08/975,573, which is incorporated into the instant application by reference.

Claim 1 has been amended to recite delivery to an extravascular cell. Support for the amendment can be found in the specification on page 19, first paragraph.

Claims 5 and 6 have been amended to recite delivery to liver and muscle cells respectfully. Support for the amendments can be found in the specification on page 11, last paragraph and bridging to page 12; page 18, second paragraph; and page 37, last paragraph.

Claim 9 has been amended to recite injection of nucleic acid into tail vein. Support for the amendment can be found in the specification on page 11, last paragraph and bridging to page 12; page 18, last paragraph; page 21, description for figure 1; example 5 starting on page 39; examples 6 and 7 on page 41; and example 8 on page 42.

Claim 12 has been amended to recite induction on an immune response in a rodent. Support for the amendment can be found in the specification on page 18, last paragraph; page 35, last paragraph; page 35, first full paragraph; and in the examples.

Claim 25 has been amended to recite a method for generating an immune response in a rodent. Support for the amendment can be found in the specification on page 10, last paragraph; page 20 second full paragraph; and page 35 to page 36.

Claim 26 has been amended to recite complexation of the nucleic acid with a polymer, which was present in original claims 25, 26 and 27.

Claim 27 has been amended to recite induction of an immune response in a mouse. Support for the amendment can be found in the specification on page 35 to page 36.

Claims 1, 2, 4, 10-12, and 26 have been rejected under 35 U.S.C. 102(b) as being anticipated by Fu et al 1997. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Fu teaches intramuscular injection of nucleic acid to induce an immune response and does not contemplate intravascular delivery.

Claims 1, 2, 7, 10-12 and 25 have been rejected under 35 U.S.C. 102(b) as being anticipated by Gregoriadis et al 1997. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Gregoriadis teaches intramuscular injection of lipid-associated nucleic acid to induce an immune response and does not contemplate intravascular delivery.

Claims 1, 2, 4, 7, 10-12, 25 and 26 have been rejected under 35 U.S.C. 102(b) as being anticipated by Ishii et al 1997. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Ishii teaches intramuscular, intraperitoneal, subcutaneous, intradermal and intranasal injection of cationic lipid-associated nucleic acid to induce an immune response and does not contemplate intravascular delivery.

Claims 1-3, 6-12, 25 and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Roy et al 1999. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Roy teaches oral immunization with DNA/chitosan particles with expression in intestinal epithelium and does not contemplate intravascular delivery.

Claims 1-12 and 25-27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Guy et al 1999. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Guy does not contemplate intravascular delivery of nucleic acid. Guy defines systemic administration as follows: "The administration of the first inducing agent may advantageously be carried out in a single dose, by systemic injection, such as an intravenous, intramuscular, intradermal or subcutaneous injection." For DNA administration, Guy solely teaches, in example 4, "the intranasal (IN) route, the intramuscular (IM) route and the intradermal (ID) route are used." Nowhere does Guy provide any teaching for a method by which an immune response is obtained by delivery of DNA via an intravenous route.

Claims 1-4, 6-12, 25 and 27 have been rejected under 35 U.S.C. 102(b) as being anticipated by Compans 1998. Applicants have amended the claims to obviate the rejection. Specifically claims 1 and 25 have been amended to incorporate the limitation of claim 5. It is the Applicants' opinion that Compans teaches delivery of DNA to mucosal surfaces and does not contemplate intravascular delivery of nucleic acid.

Claims 1-3, 5, 7, 10-12, 25 and 26 have been rejected under 35 U.S.C. 102(b) as being anticipated by Content et al 1998 and Donnelly et al 1996. Applicants have amended the claims to obviate the rejections. Specifically claims 1 and 25 have been amended to

incorporate the limitation of claim 5. Claim 1 has been further amended to recite the limitation of elevating intravascular pressure and increasing vascular permeability. Support for the amendment can be found in the specification on page 18, last paragraph; page 19, lines 1-9; page 19, last paragraph; and in U.S. patent Application no. 08/975,573, which is incorporated by reference into the instant application. Claim 25 has been amended to recite the limitation of injection into the tail vein of a rodent. Support for the amendment can be found on page 18, last paragraph; examples 5-8, starting on page 39; and in US patent Application no. 08/975,573, which is incorporated by reference into the instant application. It is the Applicants' opinion that Donnelly does not teach or provide motivation for injection of nucleic acid into a vessel and increasing vascular pressure and permeability or injection into the tail vein of a rodent.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-12 and 25-27 should be allowable. Applicants respectfully request a timely Notice of Allowance be issued in the case.

Respectfully submitted,

Mark K. Johnson Reg. No. 35,909
Mirus
505 South Rosa Road
Madison, WI 53719
608-238-4400

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as express mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this date: 7/2/04

Kirk Ekena